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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,346	09/27/2000	Robert Lamb		4446

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/670,346	LAMB, ROBERT	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 5-5-06 is acknowledged.

Claims included in the prosecution are 27-67.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 27-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to what applicant considers as 'polyenyl phosphatidylcholine' as recited in claims 27 and 48. A careful review of the specification indicates the use of soybean phosphatidylcholine. While the term, 'polyenyl' represents two or more double bonds; soybean phosphatidylcholine contains fatty acids besides linoleic, linolenic and oleic acids. Clarification is requested.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant provides definitions which are not supported by any evidence. The attachments submitted do not define this term. The rejection is maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-29, 31, 33-40, 44-46, 48-50, 52, 54-61 and 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/15731.

WO 93 teaches liposomal compositions containing vitamin E phosphate and a method of protecting cells from chemically induced injury and stimulating cell repair. The chemicals taught are ethanol and allyl alcohol. The administration is done by various claimed modes. The composition is also taught to be administered directly into the tissues during or following transplant or surgery (note the abstract, pages 3-12 and claims).

Although WO does not specifically teach that the phosphatidylcholine is from soybeans (polyenyl phosphatidylcholine) since the examples and the results obtained in both WO and instant invention are identical (see example 2 in instant specification and example 9 in the reference, the use of the same phosphatidylcholine is implicit.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 27- 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15731 cited above in combination with Aleynik et al (J, Investigative Medicine, 1999) or perricone (6,191,121).

The teachings of WO have been discussed above. As pointed out above, although WO does not specifically teach that the phosphatidylcholine is from soybeans (polyenyl phosphatidylcholine) since the examples and the results obtained in both WO and instant invention are identical (see example 2 in instant specification and example 9 in the reference, the use of the same phosphatidylcholine is implicit.

Aleynik teaches that polyenylphosphatidylcholine prevents fibrosis induced by alcohol and CCl4 and opposes the associated oxidative stress (abstract, Introduction and discussion).

Perricone while disclosing treatment of skin damage using polyenylphosphatidylcholine teaches that this compound itself is an active antioxidant that protect against lipid peroxidation and liver damage (col. 5, lines 22-52).

Assuming that the phosphatidylcholine taught by WO is not a polyenylphosphatidylcholine, it would have been obvious to one of ordinary skill in the art to prepare liposomes made of polyenylphosphatidylcholine in WO since this compound itself is an antioxidant, prevents oxidative stress as taught by Alenik, and Perricone and one would expect at least an additive effect. What is lacking in WO is the teaching that the oxidative stress is due to iron. However, the reference clearly teaches that vitamin E phosphate is effective in protecting against the oxidative damage caused by chemicals and illustrates using some chemicals. It would have been

obvious to one of ordinary skill in the art therefore, with a reasonable expectation of success

that vitamin E phosphate will be effective irrespective of which chemical causes the oxidative damage. WO also does not teach oral administration of the composition and that the composition could be administered in a beverage. However, in view of WO's teachings on page 4, lines 1-5 that the route of administration of VEP will depend on the target organ, one of ordinary skill in the art would be motivated to use any mode of administration including oral administration and in a beverage form with a reasonable expectation of success.

7. Claims 35-36, 41, 56-57 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15731 by itself or in combination with Aleynik et al (J, Investigative Medicine, 1999) or Perricone as set forth above, in combination with Mehansho et al (5,888,563).

The teachings of WO and Perricone have been discussed above. As pointed out above, WO does not specifically teach the claimed modes of administration.

Mehansho et al teach food and beverage products, chewing gums and lozenges which contain liposomes (bilayers). The compositions contain vitamin E (tocopherol) (abstract, col. 8, line 43 through col. 9, line 41col. 11, line 67 through col. 12, line 21, Examples VI and VII and claims).

It would have been obvious to one of ordinary skill in the art to deliver the compositions of WO, WO, Aleynik, and Perricone orally or mucosally and using beverage products with a reasonable expectation of success since the reference of

Mehansho shows that vitamin E containing compositions can be administered using these means.

8. Claims 32, 43, 53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15731 by itself or in combination with Aleynik et al (J, Investigative Medicine, 1999) or Perricone as set forth above, in combination with Hendler (5,114,957),

The teachings of WO and Perricone have been discussed above. What is lacking in WO is the teaching of oral administration in the form of capsules. This mode of administration however, would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Hendler teaches that vitamin E phosphate compositions can be administered as capsules (col. 5, lines 34-47).

9. Claims 32, 36, 42, 53, 57, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/15731 by itself or in combination with Aleynik et al (J, Investigative Medicine, 1999) or Perricone as set forth above, in combination with Pest (4,439,432).

The teachings of WO have been discussed above. What is lacking in WO is the teaching of the administration in the form of a suppository. This mode of administration however, would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pest teaches that vitamin E compositions can be administered as suppositories or orally (abstract and claims).

Applicant's arguments to the above rejections have been fully considered, but are not found to be persuasive. Applicant amends the continuation data and argue that

the priority of the application goes back to Feb. 14, 1992 and therefore the WO reference is not prior art. These arguments are not persuasive. This application is a continuation in part of 09/368,173 filed on August 5, 1999 which is a continuation in part of application 08/347,167 filed on November 23, 1994 which in turn is a continuation of 08/109,486 filed on August 20, 1993 which in turn is a continuation in part of 07/836,085 filed Feb. 14, 1992. A careful examination of 09/368,173 application shows that there is no support for the term 'polyenylphosphatidylcholine'. The filing date of this application is August 5, 1999. The WO reference therefore, is still applicable prior art and the rejections are maintained.

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK